TRANSCRIPT OF RECORD.

SUPREME COURT OF THE UNITED STATES.

OCTOBER TERM, 1911.

No. ~~836~~. 118

THE UNITED STATES OF AMERICA, PLAINTIFF IN ERROR AND APPELLANT,

vs.

THE ANTIKAMNIA CHEMICAL COMPANY.

IN ERROR TO AND APPEAL FROM THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA.

FILED OCTOBER 17, 1911.

(22,912.)

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INDEX.

JUDD & DETWEILER (INC.), PRINTERS, WASHINGTON, D. C., OCTOBER 30, 1911.

Act of Congress in such case made and provided, approved June thirtieth, A. D. 1906 (Part 1, Vol. 34, U. S. Statutes at Large, p. 738, commonly known as the Food and Drugs Act).

2 II.

Your libelant represents to this Honorable Court that in the City of Washington, in the District of Columbia, and within the jurisdiction of this Honorable Court, are, to wit, one hundred packages, more or less, of a certain drug used and intended to be used for the cure and mitigation and prevention of disease of man, particularly described as follows:

Twenty packages, more or less, of said drug, labelled and branded as follows: "Antikamnia Tablets. Contain 305 grains of acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906. U. S. Serial Number 10. The Antikamnia tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. Antikamnia tablets five grains. One ounce Antikamnia Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A."

Also seventy other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Codein Tablets. Contain 296 grains acetphenetidin, U. S. P. per ounce. Contain 18 grains sulp. codein per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906, U. S. Serial number 10. The Antikamnia and Codein tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, heroin, cocaine, alpha, or beta eucaine, arsenic, strych-ine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Codein Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A."

Also ten other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Quinine Tablets. Contain 165 grains acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30, 1906, U. S. Serial Number 10. The Antikamnia and Quinine Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strych-ine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Quinine Tablets. Manufactured in the United States of America by the Antikamnia Chemical Co., St. Louis, U. S. A."

Your libelant further represents that the said one hundred packages, more or less, particularly described as aforesaid, are now in the possession and custody of The Washington Wholesale Drug Exchange, a body corporate, at premises, to wit, numbered four hundred and fifty-nine on C Street, North-west, in the City of Washington, District of Columbia.

III.

Your libelant further represents that the said one hundred packages, more or less, of said drug, as aforesaid particularly described, are illegally held within the jurisdiction of this Honorable Court, for that the same are misbranded in violation of the aforesaid Act of Congress approved June thirtieth, A. D. 1906, and are
3 liable to confiscation and condemnation as provided therein, for the reasons following:

Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said Act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libelant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin contained therein is a derivative of acetanilid, or that the said drug contains any derivative of acetanilid.

Your libelant further charges that each and all of said packages of drug are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug.

IV.

Your libelant further represents that all the matters above set forth are true; that the said packages of said drug are now in the possession and custody of the said The Washington Wholesale Drug Exchange, a body corporate, as aforesaid, at the premises aforesaid, and are now being sold and offered for sale by said body corporate within the District aforesaid.

Wherefore, the premises considered, your libelant prays:

1. That the said packages of said drug be proceeded against and seized for condemnation in accordance with the provisions of the said Act of Congress, and that to this end this Honorable Court may order a warrant of arrest to issue in due form of law, according to the course of this Honorable Court in cases of admiralty, so far as is applicable in this case, and that the said The Washington Wholesale Drug Exchange, a body corporate, and all other persons having or pretending to have any right, title or claim in and to the said drug, may be cited to appear herein and answer all and singular the premises aforesaid.

2. That by a proper order this Honorable Court may adjudge and decree that the said packages of said drug and each and all thereof be condemned at the suit of this libelant, according to the provisions of the said Act of Congress; and that the same may be disposed of by sale, under such terms and conditions as this Honorable Court, by a proper order shall provide; and that the proceeds thereof, less legal

costs and charges, by a proper order, may be directed to be paid into the Treasury of the United States.

3. That this Honorable Court may pass all such orders, decrees and judgments as may be necessary in the premises, and may grant your libelant a decree for the costs of this proceeding, against the owners or the holders of said drug so condemned, should such costs not be paid out of the proceeds of the sale of same, or otherwise.

And that your libelant may have such other and further
4 relief as the nature of the case may require.

CLARENCE R. WILSON,
Attorney of the United States in and
for the District of Columbia.

DISTRICT OF COLUMBIA, *ss:*

I, Clarence R. Wilson, being first duly sworn, on oath say that I am the Attorney of the United States in and for the District of Columbia; that I have read over the foregoing libel by me subscribed, and know the contents thereof; that the matters and things therein stated of my own knowledge are true, and those stated on information and belief I believe to be true.

CLARENCE R. WILSON.

Subscribed and sworn to before me this 7 day of July, A. D. 1910.

J. R. YOUNG, *Clerk,*
By R. P. BELEW, *Asst. Clerk.*

Endorsed: Let the warrant issue herein as prayed, returnable on the 4th day of August, A. D. 1910, at 10:30 A. M.

WENDELL P. STAFFORD, *Justice.*

Warrant of Arrest.

Filed Jul- 12, 1910.

* * * * * * *

The President of the United States to the Marshal for said District, Greeting:

For the reasons stated in the Libel, herein filed on the 7th day of July 1910, by Clarence R. Wilson, U. S. Attorney, D. C.

You are hereby commanded to arrest the said 20 packages, more or less, labeled "Antikamnia Tablets; the said 70 packages, more or less, labeled "Antikamnia and Codein Tablets", and the said 10 packages, more or less, labeled "Antikamnia and Quinine Tablets", in possession and on premises of The Washington Wholesale Drug Exchange, 459 C Street, N. W., Washington, D. C. and detain the same until further order of the Court; and to warn all persons having any claim or interest therein, to be and appear before said Court on the 4th day of August 1910, at 10.30 A. M., to answer said libel;

and that in case of failure to appear the Court will proceed to determine the cause, and to make such order therein as to it shall seem right.

Witness The Honorable Harry M. Clabaugh, Chief Justice of said Court, the 7th day of July, A. D. 1910.

[SEAL.]

J. R. YOUNG, *Clerk*,
By F. E. CUNNINGHAM,
Assistant Clerk.

_____,
U. S. Attorney.

5

Marshal's Return.

Arrested 20 packages labeled Antikamnia Tablets, 10 packages labeled Antikamnia and Quinine Tablets and 63 packages labeled Antikamnia and Codein Tablets and in custody. Served copy of the writ on the Washington Wholesale Drug Exchange by service on Wymond H. Bradbury, Manager, personally and tacked a copy of the writ on the Court House door all this 7th day of July 1910.

AULICK PALMER, *Marshal*.
H.

Petition.

Filed Oct. 3, 1910.

* * * * * * *

Your petitioner, the Antikamnia Chemical Company, respectfully represents:

First. That it is a corporation duly incorporated.

Second. That it is the true and bona fide owner of the several packages of tablets mentioned in the second paragraph of the libel filed in the above entitled cause, and that no other person is the owner thereof, and that as such owner, it desires to intervene and be made a defendant in said libel in order that it may protect its rights to the said packages mentioned in said second paragraph of said libel.

Wherefore, your petitioner prays that this honorable Court pass an order, making your petitioner a defendant in said suit and giving to your petitioner all rights that it may have as such defendant to raise questions of law and fact in said suit, and such other and further relief as this petition may require.

THE ANTIKAMNIA CHEMICAL CO.,
By FRANK A. REEF, *President*.

BAKER, SHEEHY & HOGAN,
Attorneys for Petitioner.

Frank A. Reef, being first duly sworn, deposes and says that he is the President of The Antikamnia Chemical Company, petitioner

in the above entitled cause, and that he has read said petition and that the facts therein stated are true.

FRANK A. REEF.

Subscribed and sworn to before me this first day of October, A. D. 1910.

[SEAL.] JAMES J. McDONALD.
Notary Public in and for the City of St. Louis, Mo.

My term expires Sept. 28, 1912.

Order.

Filed Oct. 3, 1910.

* * * * * * *

Upon consideration of the petition of The Antikamnia Chemical Company, it is this 3rd day of October 1910,

6 Ordered that the said petitioner, The Antikamnia Chemical Company, be and it is hereby made a defendant in the above entitled cause with full rights to litigate any questions that may arise therein.

By the Court.

HARRY M. CLABAUGH.
Chief Justice.

Exceptions to Libel.

Oct. 3, 1910.

* * * * * * *

Now comes the defendant, The Antikamnia Chemical Company, owner of the packages mentioned in the second paragraph of the libel filed in the above entitled cause, and objects and excepts to the seizure of the several packages mentioned in said libel, and objects and excepts to the said libel and says that the said libel is bad in substance and does not contain any statement of fact or allegation to warrant the seizure of the said packages mentioned in said libel and the condemnation thereof because the said defendant severally says:

1. That said packages referred to in said libel are not misbranded in violation of the Act of Congress approved June 30, 1906, entitled "The Food and Drugs Act," and are not liable to confiscation and condemnation under said Act, because each and all of said packages are properly marked and properly state the proportion of acetphenetidin contained therein and that they are properly labeled under said Act.

2. That the said Act does not require that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid, nor is it necessary under said Act that a derivative of any parent substance should state that

it is a derivative of such substance, provided the derivative itself is named by its proper name.

3. That the said packages are not misbranded, in that each and all of the said labels bear the statement that no acetanilid is contained therein because, according to the allegation of said libel, there is nothing in said statement that is in any way false and misleading, nor does said statement import or signify that there is no quantity or proportion of any derivative of acetanilid contained in said drug.

4. That said statement on said packages that each and all of said labels bear the statement that no acetanilid is contained therein is in no way false or misleading, because said libel does not allege that there is any acetanilid in said packages, and, therefore, said statement, instead of being false and misleading, is, according to the allegations of said libel, true.

5. That said libel does state that in said packages is contained acetphenetidin and the other statement on said package that said package contains no acetanilid could in no way be false and misleading because, according to the allegations of said libel, the same is true.

7 6. That said libel charges that acetphenetidin is a derivative of acetanilid, but does not charge that there is any acetanilid in acetphenetidin and, therefore, the statement as contained on the label of said packages, that there is no acetanilid contained in said packages, is, according to the averments and allegations of said libel, true.

7. That said Act of Congress of June 30, 1906, provides in section 8:

"* * * or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein."

And does not provide that there should be added to any derivative of any such substance as contained therein the name of said parent substance and said Act of Congress cannot be added to or enlarged by requiring this defendant, or any person, to add to a known substance the fact that the same is a derivative of any of the substances mentioned in the above paragraph.

8. Defendant further objects and excepts to the following paragraph in section 3 of said libel:

"Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said Act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libelant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin contained therein is a derivative of acetanilid, or that the said drug contains any derivative of acetanilid."

And says that same is bad in substance because there is nothing in said Act of Congress, approved June 30, 1906, that requires the labeling of the said packages as set out in said paragraph.

9. Defendant further objects and excepts to the following paragraph in section 3 of said libel:

"Your libelant further charges that each and all of said packages of drug are further misbranded, in that the labels thereon are false and misleading, for the reason that each and all of said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug."

And says that the same is bad in substance because it says that in said libel there is no allegation, either direct or indirect, that there is any acetanilid contained in said drug, and because the statement that there is no acetanilid contained in said drug in no way imports or signifies that there is no quantity or proportion of a derivative of acetanilid.

Wherefore, your defendant prays that the said exceptions and objections to said libel be severally sustained, that said libel be dismissed and said packages mentioned in said libel be restored
8 to your petitioner as the owner thereof, and that costs be awarded against the United States for unlawfully seizing the said packages.

BAKER, SHEEHY & HOGAN,
Attorneys for Defendant.

Decree.

Filed Nov. 21, 1910.

* * * * * * *

This cause coming on to be heard upon the libel and the exceptions and objections filed thereto, and the same having been argued by counsel for the respective parties, and having been fully considered by the court, it is this 21st day of November, A. D. 1910,

Ordered, adjudged and decreed: That said exceptions and objections to said libel be, and the same are, hereby sustained, and that the said libel be, and the same is, hereby dismissed, and that the goods seized be, and the same are, hereby discharged from said seizure and ordered returned to the Defendant, the Antikamnia Chemical Company, without cost to the Defendant.

HARRY M. CLABAUGH,
Chief Justice.

From this decree the United States, in open court pray an appeal to the Court of Appeals, which is hereby granted, this 21st day of November, 1910, and it is hereby ordered that, pending said appeal, the said goods remain in the custody of the Marshal.

HARRY M. CLABAUGH,
Chief Justice.

Stipulation.

Filed Dec. 7, 1910.

* * * * * * *

It is hereby stipulated and agreed by and between Clarence R. Wilson, Attorney of the United States in and for the District of Columbia, on behalf of the United States of America, libelants, and Daniel W. Baker, attorney for the claimant in the above entitled cause, that Food Inspection Decision No. 112, issued January 27, 1910, by the United States Department of Agriculture, was considered by this Court upon the hearing of the above cause, and that the said Food Inspection Decision shall be included in and considered as a part of the record of this cause on appeal, this Court having taken judicial notice thereof.

CLARENCE R. WILSON,
Attorney of the United States in and for the District of Columbia.

DANIEL W. BAKER,
Attorney for Claimant.

9 F. I. D. 112. Issued January 27, 1910.

UNITED STATES DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
BOARD OF FOOD AND DRUG INSPECTION.

Food Inspection Decision 112.

Amendment to Regulation 28 (Labeling of Derivatives).

Section 8 of the Food and Drugs Act of June 30, 1906, paragraph "Second," under "Drugs," provides that a drug shall be deemed to be misbranded "if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein."

In an opinion rendered January 15, 1909, the Attorney-General held that a derivative within the meaning of this section of the act is a substance which is so related to one of the specified substances "that it would be rightly regarded by recognized authorities in chemistry as obtained from the latter 'by actual or theoretical substitution,' and it is not indispensable that it should be actually produced therefrom as a matter of fact," and, further, that the labeling of derivatives, as prescribed by this section, is a proper subject conferred upon them by section 3, and that a rule or regulation requiring the name of the specified substance to follow that of the derivative would be in harmony with the general purpose of the act, and an appropriate method by which to give effect to its provisions.

In conformity with this opinion, the Board of Food and Drug Inspection recommends that Regulation 28 of the Rules and Regulations for the enforcement of the Food and Drugs Act, published in Circular 21 of the Office of the Secretary, be amended by the addition, to follow paragraph (*f*), of a new paragraph to be designated as paragraph (*g*), reading as follows:

(*g*) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance.

10 This paragraph (*g*) prescribes, in effect, that in labeling derivatives the name of the specified substance must be stated, so as to clearly indicate that the product is a derivative of the particular substance named in the act.

Regulation 28 as amended shall be effective on and after April 1, 1910, and the regulation in full shall read as follows:

Regulation 28.—*Substances Named in Drugs or Foods.*

(Section 8, Second under "Drugs"; Second under "Foods.")

(*a*) The term "alcohol" is defined to mean common or ethyl alcohol. No other kind of alcohol is permissible in the manufacture of drugs except as specified in the United States Pharmacopœia or National Formulary.

(*b*) The words alcohol, morphine, opium, etc., and the quantities and proportions thereof, shall be printed in letters corresponding in size with those prescribed in Regulation 17, paragraph (*c*).

(*c*) A drug, or food product, except in respect of alcohol, is misbranded in case it fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, heroin, cocaine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

(*d*) A statement of the maximum quantity or proportion of any such substances present will meet the requirements, provided the maximum stated does not vary materially from the average quantity or proportion.

(*e*) In case the actual quantity or proportion is stated it shall be the average quantity or proportion with the variations noted in Regulation 29.

(*f*) The following are the principal derivatives and preparations made from the articles which are required to be named upon the label:

Alcohol, Ethyl (cologne spirits, grain alcohol, rectified spirits, spirits, and spirits of wine).

Derivatives—Aldehyde, ether, ethyl acetate, ethyl nitrite, and paraldehyde.

Preparations containing alcohol—Bitters, brandies, cordials, elixirs, essences, fluid extracts, spirits, sirups, tinctures, tonics, whiskies, and wines.

Morphine, Alkaloid:

Derivatives—Apomorphine, dionine, peronine, morphine, acetate, hydrochloride, sulphate, and other salts of morphine.

Preparations containing morphine or derivatives of morphine—Bougies, catarrh snuff, chlorodyne, compound powder of morphine, crayons, elixirs, granules, pills, solutions, sirups, suppositories, tablets, triturates, and troches.

Opium Gum:

Preparations of opium—Extracts, denarcotized opium, granulated opium, and powdered opium, bougies, brown mixture, carminative mixtures, crayons, dover's powder, elixirs, liniments, ointments, paregoric, pills, plasters, sirups, suppositories, tablets, tinctures, troches, vinegars, and wines.

Derivatives—Codeine, alkaloid, hydrochloride, phosphate, sulphate, and other salts of codein.

Preparations containing codein or its salts—Elixirs, pills, sirups, and tablets.

U-12 Cocaine, Alkaloid:

Derivatives—Cocaine hydrochloride, oleate, and other salts.

Preparations containing cocaine or salts of cocaine—Coca leaves, catarrh powders, elixirs, extracts, infusion of coca, ointments, paste, pencils, pills, solutions, sirups, tablets, tinctures, troches, and wines.

Heroin:

Preparations containing heroin—Sirups, elixirs, pills, and tablets.

Alpha and Beta Eucaine:

Preparations—Mixtures, ointments, powders, and solutions.

Chloroform:

Preparations containing chloroform—Chloranodyne, elixirs, emulsions, liniments, mixtures, spirits, and sirups.

Cannabis Indica:

Preparations of cannabis indica—Corn remedies, extracts, mixtures, pills, powders, tablets, and tinctures.

Chloral Hydrate (Chloral, U. S. Pharmacopœia, 1890):

Derivatives—Chloral acetophenonoxim, chloral alcoholate, chloralamide, chloralimide, chloral orthoform, chloralose, dormiol, hypnal, and uraline.

Preparations containing chloral hydrate or its derivatives—Chloral camphorate, elixirs, liniments, mixtures, ointments, suppositories, sirups, and tablets.

Acetanilide (Antifebrine, Phenylacetamide):

Derivatives—Acetphenetidine, citrophen, diacetanilide, lactophenin, methoxy-acetanilide, methylacetanilide, para-iodoacetanilide, and phenacetine.

Preparations containing acetanilide or derivatives—Analgesics, antineuralgics, antirheumatics, cachets, capsules, cold remedies, elixirs, granular effervescing salts, headache powders, mixtures, pain remedies, pills, and tablets.

(*g*) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance.

H. W. WILEY,
F. L. DUNLAP,
GEO. P. McCABE,
Board of Food and Drug Inspection.

Approved:

FRANKLIN MacVEAGH,
Secretary of the Treasury.
JAMES WILSON,
Secretary of Agriculture.
CHARLES NAGEL,
Secretary of Commerce and Labor.

Washington, D. C., January 6, 1910.

13 *Directions to Clerk for Preparation of Transcript of Record.*

Filed Dec. 7, 1910.

* * * * * * *

The Clerk of the Court will please prepare transcript of record in the above entitled cause, and include therein the following:

1. Libel filed July 7, 1910, and fiat.
2. Warrant of Arrest and Marshal's return thereon.
3. Petition of owner to be made defendant, and order thereon, filed October 3, 1910.
4. Exceptions to libel, filed October 3, 1910.
5. Decree sustaining exceptions and dismissing libel; appeal noted in open court by libelants, and order of court thereon, filed November 21, 1910.
6. Stipulation as to record, and Food Inspection Decision 112, filed Dec. 7, 1910.
7. This designation.

CLARENCE R. WILSON,
Attorney of the United States in and for the District of Columbia.

The foregoing is satisfactory.

DANIEL W. BAKER,
Attorneys for Claimant.

Supreme Court of the District of Columbia.

UNITED STATES OF AMERICA,
District of Columbia, ss:

I, John R. Young, Clerk of the Supreme Court of the District of Columbia, hereby certify the foregoing pages numbered from 1 to 18, both inclusive, to be a true and correct transcript of the record, according to directions of counsel herein filed, copy of which is made part of this transcript, in cause entitled The United States of America, libelant, vs. One Hundred Packages, more or less of "Antikamnia Tablets," No. 883, District Court Docket, as the same remains upon the files and of record in said Court.

In testimony whereof, I hereunto subscribe my name and affix the seal of said Court, at the City of Washington, in said District, this 15th day of December, 1910.

[Seal Supreme Court of the District of Columbia.]

JOHN R. YOUNG, *Clerk.*

Endorsed on cover: District of Columbia Supreme Court. No. 2257. The United States of America, appellant, vs. The Antikamnia Chemical Company. Court of Appeals, District of Columbia. Filed Dec. 19, 1910. Henry W. Hodges, clerk.

14

No. 2257.

THE UNITED STATES OF AMERICA, Appellant,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

FRIDAY, *April 7th*, A. D. 1911.

The argument in the above entitled cause was commenced by Mr. S. C. Peele, attorney for the appellant, and was continued by Mr. D. W. Baker, attorney for the appellee.

No. 2257.

THE UNITED STATES OF AMERICA, Appellant,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

MONDAY, *April 10th*, A. D. 1911.

The argument in the above entitled cause was continued by Mr. D. W. Baker, attorney for the appellee, and was concluded by Mr. Clarence R. Wilson, attorney for the appellant.

On motion the appellee is allowed five days to file an additional brief herein if so advised.

15 No. 2257.

UNITED STATES OF AMERICA, Appellant,
v.
ANTIKAMNIA CHEMICAL COMPANY.

Opinion.

Mr. Chief Justice Shepard delivered the opinion of the Court:

This is an appeal by the United States from a judgment sustaining exceptions to, and dismissing a libel.

The libel prayed the seizure and condemnation of one hundred packages of a certain drug describing the same as follows:

Twenty packages, more or less, of said drug, labelled and branded as follows: "Antikamnia Tablets. Contain 305 grains of acetphenetidin, U. S. P. per ounce, Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30th, 1906, U. S. Serial Number 10. The Antikamnia Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. Antikamnia Tablets five grains. One ounce Antikamnia Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company, St. Louis, U. S. A."

Also seventy other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Codein Tablets. Contain 296 grains acetphenetidin, U. S. P. per ounce. Contain 18 grains supl. codein per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30th, 1906, U. S. Serial No. 10. The Antikamnia and Codein Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Codein Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company, St. Louis, U. S. A."

Also ten other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Quinine Tablets. Contain 165 grains acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30th, 1906, U. S. Serial No. 10. The Antikamnia and Quinine Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Quinine Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company of St. Louis, U. S. A."

The libel charges that the packages of said drug are subject to condemnation as misbranded in violation of the provisions of the Food and Drugs Act, approved June 30, 1906.

"Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libelant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin contained therein is a derivative of acetanilid, or that the drug contains any derivative of acetanilid.

"Your libelant further charges that each and all of said packages of drug are further misbranded in that the labels thereon are false and misleading, for the reason that each and all of the said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug."

Under the warrant ordered to issue, the marshal seized ninety-three packages in all bearing the labels aforesaid. By leave of the court, the Antikamnia Chemical Company, alleging itself to be the owner of the packages, was permitted to appear as party defendant.

The exceptions on which the libel was dismissed are substantially: That the act does not require that the label on each of said packages shall have a statement that the acetphenetidin contained therein is a derivative of acetanilide, nor is it necessary under said act that a derivative of any parent substance should state that it is a derivative of such substance, provided the derivative itself is named by its proper name. That the statement on the packages that it contains no acetanilid is neither false nor misleading, but true, and the libel while charging that acetphenetidin is a derivative of acetanilide, does not charge that there is any acetanilide in acetphenetidin.

Section 1 of the Food and Drugs Act makes it unlawful to manufacture within any territory, or the District of Columbia, an article of Food or Drug which is adulterated or misbranded, "within the meaning of this act," and imposes a penalty therefor.

16 Section 2 prohibits the introduction into any State or Territory, or the District of Columbia, and the shipment from the same to any other State, Territory, etc., or foreign country, any article of food or drug, in the original packages, adulterated or misbranded within the meaning of this act, and the sale or offer for sale in the District of Columbia or Territories of any such adulterated or misbranded foods or drugs; and provides a penalty therefor.

Section 3 provides: "That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this act, including the collection and examination of specimens of foods and drugs," etc.

Section 4 provides for the examination of foods and drugs, and the giving of notice if found to be adulterated or misbranded.

Section 5 makes it the duty of the district attorney to whom report shall be made of any violation of the act, to cause appropriate pro-

ceedings to be commenced, without delay, for the enforcement of the penalties provided in the act.

Section 6 defines the meaning and inclusion of the terms drug and food.

Section 7 declares that for the purposes of this act an article shall be deemed to be adulterated: "In case of drugs: First. If when a drug is sold under or by a name recognized in the United States Pharmacopœia, or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia, or National Formulary, official at the time of investigation: Provided that no drug defined in the United States Pharmacopœia, or National Formulary, shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia, or National Formulary.

"Second, if its strength or purity fall below the professed standard or quality under which it is sold." (Other portions of the section relate to confectionery and foods.)

SECTION 8. "That the term 'misbranded,' as used herein, shall apply to all drugs or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein, which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced. That for the purposes of this act an article shall also be deemed to be misbranded: 'In case of drugs, first, if it be an imitation of, or offered for sale under the name of, another article. Second, if the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such a package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any substances contained therein." (Remainder of section applies to foods.)

Section 9 relates to guarantees by wholesalers, jobbers, and manufacturers.

Section 10 provides for the seizure and condemnation of adulterated or misbranded foods, drugs, and liquors through proceedings instituted for the purpose, which proceedings "shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of an issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States."

Sections 11, 12, and 13 have no possible bearing on the questions involved.

Acting upon the recommendation of the commission of experts the Secretaries of the Treasury, of Agriculture, and of Commerce

and Labor, respectively, adopted certain rules and regulations for carrying out the provision of the foregoing act on October 17, 1906, and published the same.

Regulation 28 was amended to take effect on April 1, 1910. This states the derivatives of the several drugs enumerated in section 8 and names the several preparations containing them respectively. Derivatives of or from and preparations containing acetanilide are enumerated as follows:

"Acetanilide (antifebrine, phenylacetamide).

"Derivatives: Acetphenetidine, citrophen, diacetanilide, lactophenin, methoxy-acetanilide, methylacetanilide, para-iodacetanilide, and phenacetine.

"Preparations containing acetanilide or derivatives: Analgesics, antineuralgics, antirheumatics, cachets, capsules, cold remedies, elixirs, granular effervescing salts, headache powders, mixtures, pain remedies, pills, and tablets."

The regulation concludes as follows: "In declaring the quality or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of the derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance."

1. A preliminary contention on behalf of the appellants is that the act being remedial and not penal, should be liberally construed. This contention seems to be of little or no practical importance in the present case, as the substantial question presented is one of power rather than construction. Without discussion, therefore, it may be conceded that the act, while it contains penal provisions without which it could not be enforced, was enacted to remedy the great mischief resulting from the unrestricted sale of adulterated drugs and articles of food and ought to be given, where possible, a construction that will effect the general legislative intention.

2. The substantial questions for determination arise upon two propositions that have been submitted in support of the contention of error in the dismissal of the bill on the exceptions stated. The first of these is: That the packages of the drug are misbranded, because the labels fail to recite that acetphenetidin contained therein is a derivative of acetanilide.

It seems clear that this omission is not in express violation of the requirement of section 8 of the act, for the reason that the label states the true name of the drug—acetphenitidine, which,
17 though not one of those specifically named in the section, is a derivative of one of them—acetanilide.

Now, while persons skilled in chemistry and pharmacy would know that acetphenitidine is a derivative of acetanilide, it is certain that the average purchaser and user of drugs would not. For this reason, no doubt, the commission of expert chemists, whose recommendations were adopted by the three secretaries, suggested the regulation requiring the label of a derivative of one of the drugs specified in section 8 to show not only the trade name of the same, but also

the name of the substance of which it is a derivative. It is well settled that where an act of Congress has for its object the raising of revenue, the administration of the affairs committed to an executive department, as of the public lands, and the like, or the execution of the power over commerce, matters of detail looking to the promulgation of regulations for carrying the law into effect, as, for example, providing for the proceedings thereunder, the fixing of standards, brands and labels, or the ascertainment of necessary facts upon which the law may operate, may be expressly delegated to an executive officer. In such instances Congress legislates on the subject as far as is reasonably practicable, and from the recognized necessities of the case is compelled to leave to executive officers the duty of bringing about the result pointed out by the statute. U. S. v. Bailey, 9 Pet., 238; U. S. v. Caha, 152 U. S., 211; In re Kollock, 165 U. S., 526; Field v. Clark, 143 U. S., 470; Union Bridge Co. v. U. S., 204 U. S., 364; St. L. & I. M. Ry. Co. v. Taylor, 210 U. S., 281; Bong v. Campbell Art Co., 214 U. S., 236; see also Coopersville Co-operative Creamery Co. v. Lemon, 163 Fed. R., 145; Prather v. U. S., 9 App. D. C., 82; Kollock v. U. S., 9 App. D. C., 120.

On the other hand, it is equally well settled that the power conferred to make regulations for carrying the law into effect must be exercised within the powers delegated, that is to say, confined to details for regulating the mode of proceeding to carry into effect the law as it has been enacted by Congress. It can not be extended to amending, or adding to the requirements of the act itself. Morrill v. Jones, 106 U. S., 466; U. S. v. Symonds, 120 U. S., 46; U. S. v. Eaton, 144 U. S., 677; Williamson v. U. S., 207 U. S., 425.

The decisions cited mark the general boundary line between the powers that may be delegated to administrative officers and those that may not be. It remains to determine on which side of that line the power claimed in the present case falls.

It must be borne in mind that the Food and Drugs Act does not confer upon executive officers the power to prescribe the forms of brands and labels upon drugs, as was done by the Oleomargarine Act, that was considered in Kollock's case, supra. The only power conferred is that, in section 3, which provides that the three secretaries named, "shall make uniform rules and regulations for the carrying out of the provisions of this act, including the collection and examination of specimens of food and drugs," etc. * * *

Section 8 declares when an article shall be deemed to be misbranded: "First. If it be an imitation of, or offered for sale under the name of, another article." "Second. If (among other things) the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or any derivative or preparation of any such substances contained therein."

In so far as the regulation designates the several derivatives of the drugs enumerated in section 8, and the preparations containing the same, we are of the opinion that it is within the power conferred in section 3 to make uniform rules and regulations for carrying out the provisions of the act. It was not reasonably practicable for Con-

gress to ascertain and declare these several derivatives and preparations, which might then have existed, much less to anticipate those which might later come into existence and use. Having declared that the quantity or proportion of the several derivatives of the named drugs shall be stated on the labels, the ascertainment of such derivatives was a matter of detail properly confined to the executive officers in carrying out the provisions of the law. The regulation having named acetphenetidine as a derivative of acetanilide, the manufacturer complied therewith to the extent of naming the proportion of said derivative contained in the antikamnia tablets, but did not comply with the requirement of the same that it should also recite that it was, in fact, a derivative of acetanilide. The last requirement was, in our opinion, an amendment of or an addition to the act itself, and therefore beyond the powers of the executive authority. Congress reserved to itself the statement of the contents of the labels and did not require that when a drug was a derivative, merely, the name of the drug from whence derived should also be recited. Had it intended that this should be done, it would have so declared distinctly. In this respect the case is clearly differentiated from In re Kollock, supra, and comes within the rule governing the second class of cases before recited, including U. S. v. Eaton, 144 U. S., 677-688; and Williamson v. U. S., 207 U. S., 425-462. In the case last cited, the question was whether a false oath made in final proof required by a regulation of the Commissioner of the Land Office, constituted perjury. The statute made certain requirements in regard to preliminary proofs and reiterated some of them in the section relating to final proofs, but omitted the one, which by the regulations made by the Commissioner under the power conferred by the act to give effect to its provisions, was required. It was held that the power to adopt rules and regulations for the enforcement of the act could not be construed to warrant one that was in fact an addition to the act.

Since the submission of this case, the Supreme Court of the United States has rendered a decision, the opinion in which, delivered by Mr. Justice Lamar, clearly draws the line between those powers which may be delegated by Congress to an executive officer and those which may not. U. S. v. Grimaud (May 1, 1911). That was an indictment for violating a regulation of the Secretary of Agriculture relating to the use and occupancy of public forest reservations. It was said that in the nature of things it was impracticable for Congress to provide regulations for the various and varying details of the management of the forest reservations, and that it was within its power to authorize the Secretary to make such regulations as would secure the objects of such reservation, namely, to regu-
18 late the use and occupancy and preserve the forests from destruction. Having so done, it declared that "Any violation of the provisions of this act, or such rules and regulations shall be punished as provided in section 5388, R. S., as amended." The violation of such reasonable rules and regulations is "made a crime, not by the Secretary, but by Congress. The statute, not the Secretary, fixes the penalty." It is this feature of the act that differenti-

ated the case from Williamson v. U. S., supra, and other cases cited, which in our opinion furnish the rule of determination for the case at bar. Congress here prescribed what the labels should contain, and conferred no power upon the secretaries to make a regulation adding anything thereto.

3. The second proposition is this in substance: The statement on the label that the drug "contains no acetanilide" is false and misleading, and constitutes misbranding within the meaning of the act. The libel does not expressly charge that acetphenetidine contains acetanilide. If it did, there would be no doubt of the soundness of the proposition, for the exceptions necessarily admit every fact plainly alleged. But it contains no such allegation. It charges that the labels are false and misleading "for the reason that each and all of said labels bear the statement that no acetanilide is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilide contained in said drug." It is argued in support of the proposition that acetphenetidine necessarily contains some appreciable quantity or proportion of the latter drug; and it is further argued that this is a matter of common knowledge of which the court may take notice without proof. We can not agree that it is a matter of common knowledge that a chemical derivative necessarily contains, or is of the same nature as, the substance whence it may be derived. It was stated on the argument, without dissent, that very many well-known substances, including acetanilide, are derivatives of benzene or benzol. Some of these derivatives are noxious, others entirely harmless. While, therefore, acetphenetidine is a chemical derivative of acetanilide, and may be derived therefrom in practice, it is in a general sense a derivative of benzene or benzol, and may, for all that we know, be derived therefrom in actual practice for commercial use. When one wishes to ascertain the common meaning or signification of a word, resort is ordinarily had to the accredited dictionaries of the language. Murray's English Dictionary defines a chemical derivative thus: "A compound obtained from another e. g. by partial replacement." The definition of the Standard Dictionary is substantially the same. In the latest edition of Webster's International Dictionary the following definition is given: "A substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice." These definitions do not carry us very far. About as far as common knowledge goes is that chemical changes occur in substances through the subtraction or the addition of some particular element. Sometimes the mingling of several substances having chemical affinities, but respectively innocuous, may produce a deadly poison. And sometimes the subtraction of an element from a poisonous substance may produce another that is perfectly harmless. The principles that direct these combinations and control the transformations effected are beyond common knowledge. They can only become known through the special study of the science of chemistry.

Whether, then, the addition or subtraction of elements through which acetphenetidine may, in theory or in practice, be derived from

acetanilide, produces such a chemical change of substance that it may be truly said to contain no acetanilide, or produces a substance which still contains an appreciable quantity or proportion of the same, presents a question of fact which, in our opinion, must be determined on the evidence of witnesses skilled in the science of chemistry.

To authorize the introduction of evidence an issue must be raised in the pleadings.

As before pointed out, the libel does not charge that the statement that the preparation contains no acetanilide is false by reason of the fact that acetphenetidine does contain acetanilide. It carefully confines itself to the allegation that the statement is false because it does not recite that there is no quantity or proportion of any derivative of acetanilide contained therein. This clearly limits the charge of misbranding to the failure to state that acetphenetidine is a derivative of acetanilide. This is but another form of the complaint that the regulation has been violated. It does not raise an issue of fact as to whether acetphenetidine actually contains a perceptible quantity of acetanilide.

In accordance with these conclusions, the judgment will be affirmed. Affirmed.

19 April Term, 1911.

No. 2257.

THE UNITED STATES OF AMERICA, Appellant,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

Appeal from the Supreme Court of the District of Columbia.

MONDAY, *May 29th*, A. D. 1911.

This cause came on to be heard on the transcript of the record from the Supreme Court of the District of Columbia and was argued by counsel. On consideration whereof, It is now here ordered, adjudged and decreed by this Court that the decree of the said Supreme Court in this cause be, and the same is hereby, affirmed.

Per MR. CHIEF JUSTICE SHEPARD.
May 29, 1911.

20 In the Court of Appeals of the District of Columbia, April Term, A. D. 1911.

No. 2257.

THE UNITED STATES OF AMERICA, Appellants,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

Assignment of Errors.

1. The court erred in holding that the act of June 30, 1906, did not require the labels on the drug in question to bear a statement that the acetphenetidin contained therein is a derivative of acetanilid.

2. The court erred in holding the libel insufficient in point of law.

3. The court erred in holding the libel to be bad in substance.

4. The court erred in sustaining the exceptions of the claimant to the libel.

5. The court erred in dismissing the libel.

6. The court erred in sustaining the third exception to the libel.

7. The court erred in sustaining the fourth exception to the libel.

8. The court erred in sustaining the fifth exception to the libel.

9. The court erred in sustaining the sixth exception to the libel.

10. The court erred in sustaining the ninth exception to the libel.

11. The court erred in holding the charge of misbranding contained in the last paragraph of Paragraph III. of the libel
21 to be insufficient in point of law.

(Endorsed:) No. 2257. The United States of America, Appellant, vs. The Antikamnia Chemical Company. Assignment of Errors. Court of Appeals, District of Columbia. Filed Oct. 3, 1911. Henry W. Hodges, Clerk.

22 No. 2257.

THE UNITED STATES OF AMERICA, Appellant,
vs.
THE ANTIKAMNIA CHEMICAL COMPANY.

TUESDAY, *October 3d*, A. D. 1911.

It is ordered by the Court that an appeal and writ of error to the Supreme Court of the United States in the above entitled cause, prayed by Mr. John Lewis Smith, on behalf of counsel for the appellant, be and the same are hereby allowed.

23 UNITED STATES OF AMERICA, *ss:*

The President of the United States to the Honorable the Justices of the Court of Appeals of the District of Columbia, Greeting:

Because in the record and proceedings, as also in the rendition of the judgment of a plea which is in the said Court of Appeals before you, or some of you, between The United States of America, Appellant, and The Antikamnia Chemical Company, Appellee a manifest error hath happened, to the great damage of the said Appellant as by its complaint appears. We being willing that error, if any hath been, should be duly corrected, and full and speedy justice done to the parties aforesaid in this behalf, do command you, if judgment be therein given, that then under your seal, distinctly and openly, you send the record and proceedings aforesaid, with all things concerning the same, to the Supreme Court of the United States, together with this writ, so that you have the same in the said Supreme Court at Washington, within 30 days from the date hereof, that the record and proceedings aforesaid being inspected, the said Supreme Court may cause further to be done therein to correct that error, what of right, and according to the laws and customs of the United States should be done.

Witness the Honorable Edward D. White, Chief Justice of the United States, the 3d day of October, in the year of our Lord one thousand nine hundred and eleven.

[Seal Court of Appeals, District of Columbia.]

HENRY W. HODGES,
Clerk of the Court of Appeals of the District of Columbia.

Allowed by

——— ———.

24 UNITED STATES OF AMERICA, *ss:*

To The Antikamnia Chemical Company, Greeting:

You are hereby cited and admonished to be and appear at a Supreme Court of the United States, at Washington, within 30 days from the date hereof, pursuant to a writ of error, filed in the Clerk's Office of the Court of Appeals of the District of Columbia, wherein The United States of America is plaintiff in error, and you are defendant in error, to show cause, if any there be, why the judgment rendered against the said plaintiff in error as in the said writ of error mentioned, should not be corrected, and why speedy justice should not be done to the parties in that behalf.

Witness, the Honorable Seth Shepard, Chief Justice of the Court of Appeals of the District of Columbia, this 3d day of October, in the year of our Lord one thousand nine hundred and eleven.

SETH SHEPARD,
Chief Justice of the Court of Appeals of the District of Columbia.

Service accepted.

DANIEL W. BAKER,
Counsel for Antikamnia Chemical Co.

[Endorsed:] Court of Appeals, District of Columbia. Filed Oct. 5, 1911. Henry W. Hodges, clerk.

25 UNITED STATES OF AMERICA, ss:

To The Antikamnia Chemical Company, Greeting:

You are hereby cited and admonished to be and appear at a Supreme Court of the United States, at Washington, within 30 days from the date hereof, pursuant to an order allowing an appeal, filed in the Clerk's Office of the Court of Appeals of the District of Columbia, wherein The United States of America is appellant and you are appellee, to show cause, if any there be, why the decree rendered against the appellant, should not be corrected, and why speedy justice should not be done to the parties in that behalf.

Witness, the Honorable Seth Shepard, Chief Justice of the Court of Appeals of the District of Columbia, this 3d day of October, in the year of our Lord one thousand nine hundred and eleven.

SETH SHEPARD,
Chief Justice of the Court of Appeals of the District of Columbia.

Service accepted.

DANIEL W. BAKER,
Counsel for Antikamnia Chemical Co.

[Endorsed:] Court of Appeals, District of Columbia. Filed Oct. 5, 1911. Henry W. Hodges, clerk.

26 Court of Appeals of the District of Columbia.

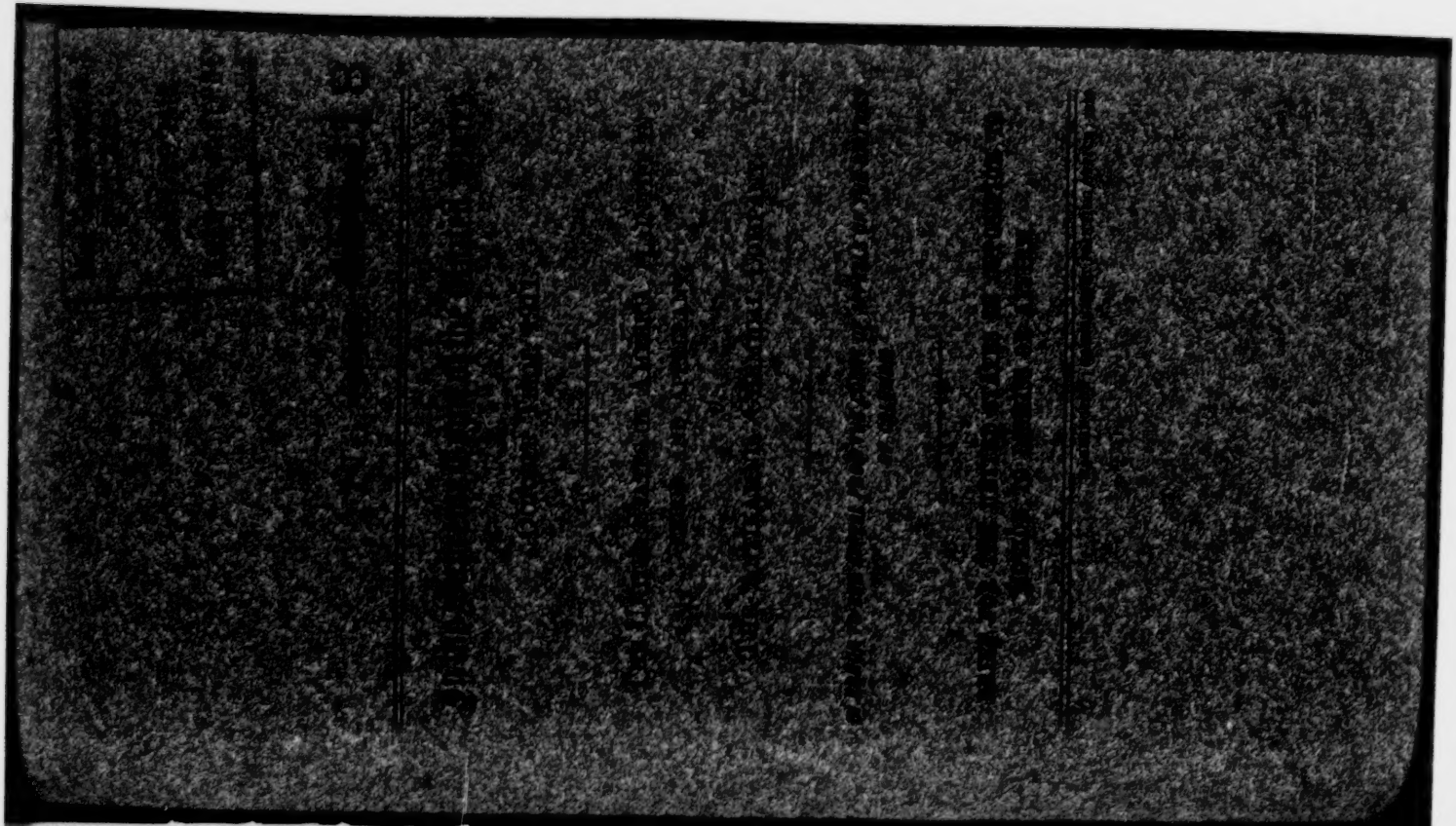
I, Henry W. Hodges, Clerk of the Court of Appeals of the District of Columbia, do hereby certify that the foregoing printed and typewritten pages numbered from 1 to 25 inclusive contain a true copy of the transcript of record and proceedings of said Court of Appeals in the case of The United States of America, Appellant, vs. The Antikamnia Chemical Company, No. 2257, October Term, 1911, as the same remains upon the files and records of said Court of Appeals.

In testimony whereof I hereunto subscribe my name and affix the seal of said Court of Appeals, at the City of Washington, this 7th day of October, A. D. 1911.

[Seal Court of Appeals, District of Columbia.]

HENRY W. HODGES,
Clerk of the Court of Appeals of the District of Columbia.

Endorsed on cover: File No. 22,912. District of Columbia Court of Appeals. Term No. 836. The United States of America, plaintiff in error and appellant, vs. The Antikamnia Chemical Company. Filed October 17th, 1911. File No. 22,912.



In the Supreme Court of the United States.

OCTOBER TERM, 1911.

THE UNITED STATES OF AMERICA, plaintiff in error and appellant,
v.
THE ANTIKAMNIA CHEMICAL COMPANY.
No. 836.

IN ERROR TO AND APPEAL FROM THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA

BRIEF FOR THE UNITED STATES IN OPPOSITION TO MOTION TO DISMISS OR AFFIRM.

This is a libel filed under the Food and Drugs Act of June 30, 1906, 34 Stat. 768. It is prosecuted for the condemnation of one hundred packages of antikamnia tablets as being misbranded.

These tablets contain acetphenetidin, which is a derivative of acetanilide. The labels upon the packages state the proportion of acetphenetidin contained in the tablets, but do not state that acetphenetidin is a derivative of acetanilide. The labels do state that the tablets contain no acetanilide. (R., 2, 3.)

The libel charges the tablets to be misbranded, because (1) the labels do not state that acetphenetidin is a derivative of acetanilide, and (2) they do

state that the tablets contain no acetanilide, and so are false and misleading as importing that no derivative of acetanilide is contained in the tablets. (R., 3.)

The exceptions to the libel are to the effect that the law does not require the first statement, and that the second is true, and so can not be false or misleading. (R., 6, 7.)

The exceptions were sustained by the Supreme Court of the District of Columbia and the libel dismissed, and this action was affirmed by the Court of Appeals. (R., 8, 21.)

The case is brought to this court by the United States, and the defendant and appellee moves to dismiss the appeal for want of jurisdiction and, failing this, to affirm the judgment on the ground that the appeal is frivolous.

The Food and Drugs Act.

so far as here involved, provides:

> SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which

they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

Section 6 defines drugs, as follows:

That the term "drug," as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.

Section 8 provides:

That the term "misbranded," as used herein, shall apply to all drugs * * * the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular. * * *

That for the purposes of this Act an article shall also be deemed to be misbranded in case of drugs:

* * * * *

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

Section 10 provides:

That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs

and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

Pursuant to the authority conferred by section 3 of the act, the Secretaries named adopted regulation 28, which, so far as here involved, provides (R., 10–12):

* * * * *

(*c*) A drug or food product except in respect of alcohol, is misbranded in case it fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, heroin, cocaine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

* * * * *

(*f*) The following are the principal derivatives and preparations made from the articles which are required to be named upon the label:

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Acetanilide (Antifebrine, Phenylacetamide):

Derivatives—Acetphenetidine, citrophen, diacetanilide, lactophenin, methoxy-acetanilide, methylacetanilide, paraiodoacetanilide, and phenacetine.

Preparations containing acetanilide or derivatives—Analgesics, antineuralgics, antirheumatics, cachets, capsules, cold remedies, elixirs, granular effervescing salts, headache powders, mixtures, pain remedies, pills, and tablets.

(*g*) In declaring the quantity or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance.

I.

The motion to dismiss the appeal.

The Court of Appeals held invalid the regulation requiring the name of the primary substance as well as that of the derivative to be stated on the

label; and there is here not only drawn in question, but so far denied, an authority exercised under the United States.

The case seems to be governed by *United States ex rel. Steinmetz* v. *Allen*, 192 U. S. 543. In that case there was a rule of practice in the Patent Office, rule 41, which provided that two or more independent inventions could not be claimed in one application. The challenge of this rule, it was insisted, did not draw in question the validity of an authority exercised under the United States, but this court said, page 556:

> By section 483 of the Revised Statutes, the Commissioner of Patents, subject to the approval of the Secretary of the Interior, is empowered to establish from time to time regulations not inconsistent with law, for the conduct of proceedings in the Patent Office. The Commissioner of Patents, exercising the power conferred, established, among other rules of practice, rule 41. It thereby became a rule of procedure and constituted, in part, the powers of the primary examiner and Commissioner. In other words, it became an authority to those officers, and, necessarily, an authority "under the United States." Its validity was and is assailed by the plaintiff in error. We think, therefore, we have jurisdiction, and the motion to dismiss is denied.

In the case at bar we have the same situation. The act of Congress provides that the Secretaries

shall make uniform rules and regulations for carrying out the provisions of the act; and the Secretaries, in pursuance of that mandate of the law, have made the regulation in question. Here, as in the *Steinmetz* case, the validity of the rule is challenged.

It was held in the *Steinmetz* case by the Supreme Court of the District and the Court of Appeals that the rule of the Patent Office was valid. This court held it to be invalid. In the case at bar the Supreme Court of the District and the Court of Appeals held the rule to be invalid, and this is the only difference between the cases. But surely the fact that the authority was upheld by the lower courts against the challenge in the one case while the challenge was sustained in the other does not alter the fact that in each case the rule was an authority under the United States and that its validity was drawn in question.

The case at bar is squarely within the rule laid down in *United States* v. *Lynch*, 137 U. S. 280, wherein it is said (p. 285):

> * * * The validity of a statute or the validity of an authority is drawn in question when the existence, or constitutionality, or legality of such statute or authority is denied, and the denial forms the subject of direct inquiry.

That is precisely the case here. The Secretaries have assumed and exercised the authority to make the regulation in question, and the very existence

or legality of the authority thus assumed and exercised by them is denied, and the denial is the subject of direct inquiry, because it is the very basis of the lower court's action.

In *Snow* v. *United States*, 118 U. S. 346, it was said (l. c., 353):

> * * * The authority exercised by the court in the trial and conviction of the plaintiff in error is not such an "authority" as is intended by the act. The validity of the existence of the court, and its jurisdiction over the crime named in the indictments, and over the person of the defendant, are not drawn in question. All that is drawn in question is whether there is or is not error in the administration of the statute.

And so in other cases cited by the appellee where the appeal was dismissed, the question was not as to the validity of the authority, but of regularity of administration under it. Here, however, as in the *Steinmetz* case, the rule or regulation is the authority under which proceedings are pending, and the question is not as to the propriety or regularity of any of the proceedings, but of the validity of the rule or regulation itself.

II.

The motion to affirm.

Section 3, as we have seen, requires that the Secretaries "shall make uniform rules and regulations for carrying out the provisions of this Act."

Pursuant to this the Secretaries have ascertained what are the derivatives in use of the various drugs named in section 8 of the act, and have prescribed that the name of the derivative shall be stated on the label of any package in the contents of which it is found. This is merely determining or ascertaining certain facts and applying to them the plain terms of the law.

The Secretaries provided also that where the derivative was required to be stated the name of the parent or primary substance should also be stated.

It is to be borne in mind that in chemistry the derivative is not necessarily, and, perhaps, not usually, obtained from the specified primary substance. It may be derived from it or it may be independently produced. The designated derivative as made by one process can not be distinguished from that derivative as made by another process. Acetphenetidin may be made from acetanilide or it may not be, but, however made, it is acetphenetidin, and it is accepted as a derivative of acetanilide because of its chemical affinity or relation to that substance. It has the same or similar therapeutic effects; it is a like kind of poison.

With respect to the drugs specifically mentioned in secton 8, Congress had a distinct purpose in mind. Adulteration was not the evil chiefly in view. The use of these drugs at all was the matter under consideration. They are all narcotics or

stimulants of the evil habit-forming kind, and the purpose of the law was to prevent people from being lured into the use of these poisons.

So, if a preparation contained opium, or any other of the specified drugs, the label must say so, and say how much. And in like manner, if the preparation contained the derivative, the label must say so, and say how much. Why was the derivative put upon the same footing with the primary drug? Not because of how it was made by man, but because of what it would do to man if he used it. The law is against selling preparations of these drugs or their derivatives without plainly informing the public by means of the labels just what the noxious stuff is in each case.

The law does not state in what language the label shall speak. So far as concerns the literal terms of the law, they would be satisfied with Sanskrit. The Secretaries, by regulation 17, have provided that the label shall speak English; and it is submitted that this is not an extension or expansion of the law, but a mere administration of it, and a failure to label in English as prescribed by the regulation would be a violation of the law itself.

The law says nothing as to the mechanical features of the label, and its literal terms would be satisfied by a microscopic legend not within the ordinary power of vision to read. The Secretaries by this same regulation have provided that the size of the type used to declare the information required

by the act shall not be smaller than 8-point (brevier) capitals, with the provision, however, that if the size of the package will not permit the use of such type the size of the type may be reduced proportionately.

The right to make such rules, and even the duty to make them, inheres in the act, and, when made, they are a part of the act, for unless the information is given in legible type and in a language intelligible to our people it is not given at all.

Now, the derivatives are by the plain terms of the law held to be as harmful as the primary substances, and the plain purpose of the law is, that the people when they buy a preparation of opium, or its derivatives, shall know that they are buying a preparation of opium, or of a derivative of opium.

And this they will not know unless they are told by the label in plain type and plain English not simply the trade name of the noxious derivative in the preparation, but of what it is a derivative.

The drugs specifically mentioned in the statute are quite generally known, but not so their many derivatives with unpronounceable and unremembrable names. We refer to pages 10 to 12 of the record. Take a few of the simpler cases. The average person is not an expert in chemical terminology, and he would not recognize morphine in dionine or peronine, or opium in codeine, or cocaine in oleate, or chloral hydrate in dormiol, hypnal, or uraline, or acetanilide in acetphenetidin, citrophen, or lacto-

phenin. To state on the label simply the trade name of a derivative, which might be whatsoever the manufacturer pleased, as, for example, para-iodoacetanilide, would be as informing as a Sanskrit label in small print.

Oleate is a derivative of cocaine, but how many people know that fact? The name is not only not suggestive but in itself misleading. The law intends that if a man buys oleate he shall know not simply that it is oleate, but that oleate is a derivative of cocaine. He is not to be lured or tricked into the use of cocaine or its equivalent, for the derivative is, in chemistry and medicine *and in this statute*, essentially an equivalent.

And so the Secretaries provided by amendment of regulation 28, as to the label, that "in declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated, *so as to indicate clearly that the product is a derivative of the particular specified substance.*" That is, make the label speak plain English. And this, we submit, does not extend the law, but only applies it.

Now, in the case at bar the labels stated simply the proportion of acetphenetidin contained in the tablets. There was nothing on the label to inform anyone not a chemical expert that the preparation contained a derivative of a drug so dangerous that the law had placed it, with its derivatives, in the

category of subtle and dangerous things; and, more than this, the label stated in terms that the tablets contained no acetanilide or other substances specified in the law—making the label display an absolute safety signal where the law positively required one of warning.

The regulation here involved bears the same relation to the case as that in *United States* v. *Bailey*, 9 Peters 238, and that in *Caha* v. *United States*, 152 U. S. 211. The statute forbids and punishes misbranding. It does not, however, describe what is proper branding, deviation from which constitutes misbranding. It left that as a matter of detail to be determined by the Secretaries. They have said that a proper branding of acetphenetidin requires the statement that it is a derivative of acetanilide. Only so does the branding give the information which the law requires. That the particular acetphenetidin in question was not, so far as concerns the process of manufacture, derived from acetanilide is not to the purpose. It is a derivative in the therapeutic sense. Not to brand it as the regulation prescribes, and beyond that to make the statement that the drug contains no acetanilide when it does contain its equivalent, is to misbrand the article and so to violate the law.

This is not the place for a full argument of the questions involved on their merits. It has been the purpose only to go far enough to show that there

is something serious to be said in support of them and that this appeal is by no means a frivolous one.

Respectfully submitted.

F. W. LEHMANN,
Solicitor General.

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